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Applicant	:	Chapoulaud et al.	Art Unit: 3732
Serial No.	:	09/941,151	Examiner: Heidi Marie Eide
Filed	:	August 28, 2001	Confirmation No.: 4585
For	:	CUSTOM ORTHODONTIC APPLIANCE FORMING METHOD AND APPARATUS	

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Commissioner of Patents
P.O. Box 1450
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Via EFS-WEB

DECLARATION OF MARK A. PAYNE

I, Mark A. Payne, hereby declare and state as follows:

1) I am a former employee of Ormco, the assignee of the above-noted patent application. I have been employed as a consultant by Ormco since leaving its employment. I am being compensated at a rate of $150 per hour for my efforts in connection with researching the facts set forth in this declaration.

2) I am one of the three inventors named in the above-noted patent application. I have reviewed the declaration of Mr. Eric Chapoulaud in connection with preparing this declaration. The paragraphs of this declaration are numbered to match those used in Mr. Chapoulaud's declaration.

Certificate of Electronic Filing

I hereby certify that this correspondence and any enclosures are being send electronically via EFS-WEB to the United States Patent and Trademark Office on the date indicated below.

4.21.2009
Date

Thomas W. Humphrey
Reg. No. 34,353

3) This application is one of several applications derived from a provisional application filed by our attorneys in late 1999, relating to the work done at Ormco over the course of several years preceding those filings.

4) The work that led to the provisional application filed in 1999, was known as the Elan project.

5) I was involved in the conception of the key concepts of the Elan project, and I was involved with Dr. Craig Andreiko in the development of working prototype software and hardware. Eric Chapoulaud joined the project later, and he was instrumental in developing additional software for customizing bracket pads, working with Dr. Andreiko. Mr. Chapoulaud's declaration elaborates his development history for various aspects of the Elan project, referencing various documents attached to his declaration. In the following paragraphs I will note those aspects of Mr. Chapoulaud's efforts which I witnessed.

6) The Elan project featured the development of software having the purpose of designing customized brackets that could be fitted to the patient's teeth. The Elan software included an extensive graphical interface for imaging the shapes of teeth, selecting landmarks on the tooth shapes to define a desired tooth repositioning, and then creating customized brackets that would guide the teeth to the desired final positions.

7) In the original versions of the Elan software, developed up to the Summer of 1996, the brackets were customized for the desired tooth positions, by placing "vanilla", or slotless, brackets into a computer controlled milling machine, that would cut customized slots

according to the desired tooth repositioning (the customization would involve establishing the torque to be applied by the archwire to the bracket, and the rotation, if any, to be achieved). This technique did not, however, permit the bracket pad to be customized to the tooth surface shape.

8) In the Summer of 1996, Eric Chapoulaud and Dr. Craig Andreiko began working on methods to enable the Elan software to directly manufacture customized brackets using rapid prototyping technology. Ultimately, these efforts led to the conception of a method for creating customized brackets by a procedure involving stereolithographic printing of bracket shapes in wax, which were converted to metal casts using an investment casting method.

9) The stereolithographic method for printing three dimensional structures was well developed at that time, and machines for creating three dimensional structures with this method were available on the market. This approach had not been applied to orthodontics up to that time, to my knowledge.

10) The investment casting method that would be used to create brackets from wax patterns, was well known at that time, and used on a daily basis within Ormco for the creation of orthodontic appliances. The use of investment casting had not been applied to creating bracket pads customized to tooth shapes up to that time, to my knowledge.

11) I have reviewed exhibits A, B, C, D, E and F attached to Mr. Chapoulaud's declaration and have no reason to question his description of those documents.

12) Exhibit A is a photograph I recall, of a wax bracket made by Mr. Chapoulaud at the offices of the West Coast distributor of Sanders Prototype Inc. of Wilton, N.H., working with their sales personnel. The brackets were evaluated at Ormco and were generally well received as discussed by Mr. Chapoulaud in his paragraph 12.

13) The July photograph in Exhibit A shows a part made only of green colored "structural" wax, which is the finished product. Immediately after the printing process, the green structural wax that forms the finished part, is encased in red colored "support" wax. The red support wax is washed away from the green structural wax after printing, to produce the finished part. In the June photograph, a bracket with some remaining support wax (colored red) can be still be seen.

14) I recall Mr. Chapoulaud pursuing the development of stereolithographic methods at Ormco, although I was not personally involved. I have no reason to question the details recited in paragraphs 14-18 of Mr. Chapoulaud's declaration.

19) Exhibit E, at the top of the second page, details the use of structural wax and support wax to build parts in a layer-by-layer fashion, as I explain above.

20) Exhibit E confirms that Sanders had a machine known as the "Model Maker" available for purchase in November 1996, and had plans to introduce an upgraded machine, the "Model Maker II", in 1997. Ormco negotiated an arrangement to purchase the "Model Maker" and upgrade it to a "Model Maker II" when the new machine became available. I recall these events.

21) The third page of Exhibit E documents Ormco's belief that it could use "Elan" software programs written by Mr. Chapoulaud, to create CAD models for direct fabrication of brackets with the Model Maker. I recall that Mr. Chapoulaud's views on that point at the time were as stated in his declaration.

22) Exhibit E also documents successful testing at Sanders. I recall that Ormco was, as stated on the third page of Exhibit E, "able to manufacture a sample of two different one piece brackets that were designed by us. These parts are the most complex parts that we have asked Sanders to make. Most particularly, their pads includes [sic] a collection of little "pegs" of 0.015 x 0.015 inches. These are very little details that are correctly reproduced by the machine."

23) I recall the capital appropriation requested using Exhibit F of Mr. Chapoulaud's declaration, and that Ormco allocated capital to purchase the Sanders Model Maker / Model Maker II for use in the Elan project. Exhibit F explains on the second and third pages that the Sanders machine had successfully created a three-dimensional bracket from a CAD design, and explains the anticipated use of the Sanders machine in automated creation of completely customized brackets including customized bracket pads to fit to the tooth shape. Specifically, the document explains that the Elan software would be improved to allow customization of bracket pads to accomplish a further improvement over the existing methods.

24) The Exhibit F capital request explains on the first page that the Model Maker would permit the Elan software to be used to directly fabricate custom brackets rather than using a milling technique to customize the brackets. I recall that this was Ormco's approach.

25) Progress in development of the Elan software to create 3D models for brackets, and to control the Sanders machine, continued through early 1997. This progress is documented in the product development reports issued by Albert Ruiz-Vela, a manager at Ormco, which were copied to myself and the other inventors, and I recall these reports. The reports of Exhibits G, H, I, J, K. L and M report on activity from December 1996 through June of 1997.

26) Exhibit G illustrates (page 4) that in December 1996, Ormco was calibrating a scanner for the purpose of scanning tooth images which would be used in creating customized brackets and pads. I recall this event.

27) Exhibit H illustrates (page 4) that in January of 1997, Ormco had the scanner operational. I recall this.

28) Exhibit I illustrates (page 4) that in February of 1997, a three dimensional scan of an upper jaw of a standard model ("P.K. THOMAS") was performed, and functions were developed in the Elan software to position CAD representations of standard "Spirit" brackets on the model of the scanned teeth. A set of brackets for an appliance was set-up on the model, and a wire to fit within those brackets was mathematically computed. I recall this.

29) Exhibit J illustrates (page 4) that in March of 1997 a case of 5x5 brackets for the upper teeth of the P.K. THOMAS model was created "manually" using CAD software; the wire and the bracket positions and characteristics (torque, in/out and RIS) were developed as part of this process. Software for automating the wire design was specified. I recall this.

30) Exhibit K illustrates (page 4) that in April of 1997 a plate was milled to thermoform the wire for the brackets defined in the previous month, and Jig design software was developed that would create bracket placement jigs for brackets. A prototype jig was milled for the upper right cuspid of the P.K. THOMAS case and was verified to have the correct precision. I recall this.

31) Exhibit L states (page 4) that in May of 1997, the Sanders machine arrived from New Hampshire, and was set up for use at Ormco. I recall this, and also recall in that month, Ormco "[p]roduced wax parts of Upper Lateral brackets in different sizes: real life, scale 10 and currently scale 20." The immediately following goals for June were to "produce customized wax patterns of brackets and JIGS, using the Elan Software."

32) I was not personally involved in the software development described in Exhibit M and explained by Mr. Chapoulaud in paragraph 32 of his declaration, however, I have no reason to question his recollections.

33) I recall, at approximately this time (June 1997), Mr. Chapoulaud using a manual process to create customized brackets, using a "subtraction" method. Specifically, in the CAD software, a standard bracket pad was placed against the patient's tooth, so that each point in the outer perimeter of the pad was at or below the tooth surface. Thereafter, any

portion of the bracket that was beneath the surface of the tooth was removed, to form a customized bracket pad shape.

34) I recall that the "manual" process was effective to create model brackets that matched tooth crown surfaces, but that it resulted in bracket pads of uneven thickness. (A slide that is part of Mr. Chapoulaud's Exhibit N, which became Fig. 5G, clearly shows brackets with uneven pad thickness created by the subtraction method described above.) This subtraction method was subsequently replaced with an automated and more robust method that created even bracket pad thickness, as noted below.

35) I do not recall the details of what prototypes were created with the Sanders machine, however, I have no reason to question the accomplishments of May of 1997 stated in Exhibit L, which included "Produced wax parts of Upper Lateral brackets in different sizes: real life, scale 10 and currently scale 20," nor do I have reason to question Mr. Chapoulaud's recollections stated in his paragraph 35.

36) I recall that by May of 1997, the Model Maker software from Sanders had been used to produce a set of brackets mounted to jigs by the stereolithography – wax investment casting method.

37) I recall that in June of 1997, a set of jigs were created for an Upper Lateral bracket set. In Exhibit M, the June progress report, it is stated that "[a] set of 5x5 Jigs have been manufactured after accuracy improvement of the manufacturing software. These jigs have been manually mounted with to their respective brackets. The case reveals good fit accuracy to the model."

38) I recall that during 1997, slides were taken for the purposes of presenting the progress of Elan. Images from a set of these slides are attached as Exhibit N to Mr. Chapoulaud's declaration. Several of the figures of the provisional application filed in 1999 were derived from these slides, and the corresponding figure numbers are shown in Exhibit N.

39) Among the slides in Exhibit N is a slide of the set of jigs created for the P.K. THOMAS model in June of 1997. Specifically, the slide shows a set of jigs dated June 11, 1997. This slide became Figure 6A of the provisional application, although the figure does not include the June 11, 1997 date that was written on the original set of Jigs. This June 11, 1997 date is documentation of the prototypes for the P.K. THOMAS tooth model mentioned in Exhibit M, although the brackets are not attached to the jigs seen in the slide.

40) I was not involved in the details of Mr. Chapoulaud's software development that are elaborated in paragraphs 40 through 45 of his declaration, but I have no reason to question the specifics of that development that are identified in those paragraphs.

46) I recall that Mr. Chapoulaud eventually demonstrated custom software that would not only create customized brackets, but also create brackets in a "tree" form. Forming brackets in a tree allowed Ormco to create multiple brackets in a single cast. At this point, the software was considered both fully "developed and tested".

47) I am not familiar with the specific automations implemented by Mr. Chapoulaud to create bracket trees as he details in paragraph 47 of his declaration, however, I have no reason to question his statements in that paragraph.

48) As stated by Mr. Chapoulaud in his paragraph 48, I recall him working very diligently on a daily basis through June and July of 1997 to develop this system.

49) I have reviewed the table of corresponding claim language of U.S. Patent 09/941,151 and specifics of the system developed at Ormco, set forth in Mr. Chapoulaud's declaration paragraph 49. Although some of the details referenced there were not personally witnessed by me (as explained above), I have no reason to question the correspondence between the claims and his activities stated in the table.

50) I was not involved in the creation of automated software linkages between various software components, and screen displays, as described by Mr. Chapoulaud in paragraphs 50-54 of his declaration; however, I have no reason to question the facts set forth in those paragraphs.

55) I recall that the finished software, for the purpose of computing a set-up of teeth, would allow an operator to identify landmarks on the images of the teeth of a patient by interaction on the screen. Based on these landmark features, the software would compute an idealized set-up of the teeth, i.e., a corrected position for the teeth.

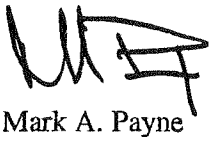
56) I recall that Dr. Craig Andreiko was very happy to have this functionality implemented and witnessed him using the software developed by Mr. Chapoulaud to landmark tooth images and create set-ups.

57) I was not involved in the process that created Exhibits U and V attached to Mr. Chapoulaud's declaration, as explained in his paragraph 57, and then related to claims of U.S. Patent Application 10/868,311 in his paragraph 58; however, I have no reason to

question the facts and their correspondence to claim language as set forth by Mr. Chapoulaud.

I declare under penalty of perjury that the foregoing is true and correct to the best of my information and belief.

Respectfully submitted,



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